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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,580	03/19/2001	Axel Ullrich	038602-1126	7851

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EXAMINER

BHATTI, TAHIRA H

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 04/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/810,580

Applicant(s)

ULLRICH ET AL.

Examiner

Tahira H Bhatti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Receipt is acknowledged of Declaration, Change of address, Extension of time, Amendment and IDS filed on 8/10/01, 5/11/01, 8/10/01, 8/10/01 and 10/9/01.

***Status of the Claims:***

2. Claims 1 is currently pending.

***Claim Rejections – 35 U.S.C. 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of modulating signal transduction by inhibiting dephosphorylation of tyrosine kinase does not reasonably provide enablement for all or any method of modulating the signal transduction. The applicant has failed to specify the modulation of signal transduction method, which, he claims to be his invention. The method as claimed, comprising inhibiting dephosphorylation of the insulin receptor type tyrosine kinase by a receptor protein phosphotyrosine phosphatase. One of an ordinary skill in the art would have to perform undue experimentation to decide which method is suitable for use to inhibit the tyrosine kinase dephosphorylation by phosphotyrosine phosphatase in order to practice the instant invention. Hence the applicant is not enabled for all the methods of modulating signal transduction, and the

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

*The factors to be considered in a determination of undue experimentation are disclosed in In re Wands (USPQ 2d 1400: CAFC 1988), which include: a. The breadth of the claims, b. The nature of the invention, c. The state of the prior art, d. The level of one of ordinary skill, e. The level of predictability in the art, f. The amount of direction provided by the inventor. g. The presence or absence of working examples h. The quantity of experimentation necessary needed to make or use the invention based on the disclosure. See :In re Wands USPQ 2d 1400 (CAFC 1) a.*

*The breadth of the claims:* The claims are drawn to a method of modulating signal transduction by inhibiting dephosphorylation of tyrosine kinase. Signal transduction modulation can be accomplished by a variety of ways see spec. page 7 lines 25-30. This represents a broad class of methods, which can include any method. This represents a broad scope.

*The nature of the Invention/State of the Prior Art:* The present invention as claimed is broadly directed to modulation of signal transduction, which can be accomplished by inhibiting dephosphorylation of tyrosine kinase. It is noted that tyrosine kinase and phosphotyrosine phosphatase., play a critical role in signal transduction mediated by the insulin receptors. And that the phosphorylation state of a protein is modified through the reciprocal actions of tyrosine kinase and phosphotyrosine

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phosphatase. However, the specific functions of these enzymes have not been defined sufficiently by the specification. There is no guidance to the nature of the enzymes involved in the specific steps of signal transduction modulation.

*The amount of direction/working examples:* The specification only provides guidance and examples directed to modulating signal transduction by inhibiting dephosphorylation of tyrosine kinase. Sufficient information of identifying a specific method of modulation of the invention, in relation to insulin receptor activity, has not been provided. This does not provide enough guidance as to the specific steps of modulating signal transduction by inhibiting dephosphorylation of tyrosine kinase. One of ordinary skill in the art is not guided enough, as to the method involved in signal transduction.

*Quantity of Experimentation:* Due to the lack of representative examples regarding modulating signal transduction by inhibiting dephosphorylation of tyrosine kinase, the amount of experimentation would be undue. Accordingly, in light of the unpredictability surrounding the cellular signal transduction and the part played by the phosphatases remains unclear, due to the lack of adequate guidance. The instant specification does not provide to one skilled in the art a reasonable amount of guidance with respect to the direction in which the experimentation should proceed in making and using the full scope of the claimed method. Note that there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed. *In re Vaeck*, 947 F. 2d 488, 496

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& n.23, 20 USPQ2d 1438, 1445& n.23 (Fed. Cir. 1991). Therefore, it is deemed that further research of an unpredictable nature would be necessary to make or use the invention as claimed. Thus, due to the inadequacies of the instant disclosure, one of ordinary skill would not have a reasonable expectation of success and the practice of the full scope of the invention would require undue experimentation.

***Claim Rejections - 35 USC § 112***

**4. The following is a quotation of the second of 35 U.S.C. 112:**

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following enumerated reasons apply.

5. Claim 1 is broader in scope. The claim does not set forth any specific steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a method without specifying any active, positive steps delimiting how this method will be used and is actually practiced.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Fantus et al., Biochem. 28: 8863-8871.

Claim 1 is drawn to a method of modulating signal transduction mediated by insulin receptor type tyrosine kinase, comprising inhibiting dephosphorylation of insulin receptor type tyrosine kinase by a receptor protein phosphotyrosine phosphatase.

Fantus et al (1989) disclosed a method of modulating signal transduction mediated by an insulin receptor type tyrosine kinase by means of pervanadate which inhibited the enzyme phosphotyrosine phosphatase (PTPase) thereby inhibiting dephosphorylation of the insulin receptor type tyrosine kinase. Vanadate was reported as known in the art to do the same (pp. 8869, Col. 1).

#### **General information regarding further correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Tahira Bhatti whose telephone number is (703) 605-1203. The examiner can normally be reached between Mondays to Friday from 8:00 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsana Venkat (art unit 1627), can be reached at (703) 308 0570. Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (702) 308-0196

***Tahira Bhatti (art unit 1627)***

***April 1, 2002***

BENNETT CELSA  
PRIMARY EXAMINER

